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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,439	06/28/2004	Kyung-Jin Kim	PISI 2 00007	2416
27885	7590	12/13/2005		
FAY, SHARPE, FAGAN, MINNICH & MCKEE, LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114			EXAMINER WIEKER, AMANDA FLYNN	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/500,439	Applicant(s) KIM, KYUNG-JIN	
	Examiner Amanda F. Wieker	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/28/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because the phrase “Disclosed is” is redundant and should be deleted. Correction is required. See MPEP § 608.01(b).
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Combined Splint for Selectively Fixing Fractures of the Foot, Leg and Knee.

### *Claim Objections*

3. Claim 1 is objected to because of the following informalities:

In claim 1 there is insufficient antecedent basis for several structural elements not previously introduced into the claims. Correction of all such problems is required, even if not specifically identified by the Examiner.

- Line 1: “the injured body part” should be amended to --an injured body part--.
- Lines 4-5: “the upper foot fixing member” and “the lower foot fixing member” should be amended to --an upper foot fixing member-- and --a lower foot fixing member--.
- Lines 7-8: “the upper connecting member” and “the lower connecting member” should be amended to --an upper foot fixing member-- and --a lower connecting member--.

4. Claim 3 is objected to because of the following informalities:

In claim 3, at line 6, there is insufficient antecedent basis for “the<sup>1</sup> front portion”. The claim should be amended to read: --a front portion-- to correct this defect.

In claim 3, at line 9, there is insufficient antecedent basis for “the bolt holes”. Amending line 6 to read: --a plurality of bolt holes-- would correct this defect.

Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "coupled to each other by means of bolts" appears to be an improper attempt to utilize 35U.S.C. 112, sixth paragraph. However, since no function is specified by a word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

7. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At line 12, it is unclear what "thereof" refers to, as it could refer to the entire lower foot fixing member, the plurality of holes, the bolt holes, the horizontal wall, or the vertical wall. Based on the specification, it appears to refer to the entire lower foot fixing member, and is being examined as such, but this should be made clearer.

8. Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As discussed in the immediately preceding paragraph, the use of the term “thereof” is unclear, when several elements are introduced in the claim prior to the term “thereof”. It is unclear which of these previously introduced elements is being referred to by “thereof”. It appears that “thereof” refers to the structure in the preamble of the claim, but this is unclear and should be corrected.

*Claim Rejections - 35 USC § 101*

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 3 and 4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Correction of all such problems is required, even if not specifically identified by the Examiner.

A claim reciting a portion of, or an attachment to, the human body contains non-statutory subject matter. 1077 OG 24 (April 21, 1987). “A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101”. Accordingly, where a claim is directed to an apparatus “attached to” the human body or any part thereof, such a claim will be rejected under 35 U.S.C. 101, because the claim positively recites a part of the human body and therefore is directed to non-statutory subject matter.

Claim 3 recites an apparatus that is attached to a part of the human body. For example, in claim 3 Applicant recites “a vertical wall in which *the sole is seated*”. Applicant also recites in claim 1: “a horizontal wall in which the *heel and the ankle are seated*”. A claim reciting a portion of, or an attachment to, the human body contains non-statutory subject matter. Similarly, in claim 4, Applicant recites, “a round part *in a close contact with the top of the foot*”.

Applicant can overcome this rejection by amending claim 3 to recite, --a vertical wall in which the sole is adapted to be seated--, and --a horizontal wall in which the heel and the ankle are adapted to be seated--. The rejection of claim 4 can be overcome by amending claim 4 to recite --a round part adapted to be in a close contact with the top of the foot--.

*Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 3,568,671 to Graham in view of U.S. Patent Number 3,762,405 to De George.

Graham discloses a combined splint and cast for immobilizing an injured body part due to fracture, ligament rupture, dislocation or the like, the combined splint and cast comprising:

a foot fixing member (12) including an upper foot fixing member (24 and 32) and a lower foot fixing member (18 of 12) which form a pair fully capable of immobilizing a region from the sole (metatarsal bones) to a portion above the ankle (below the soleus muscle), depending on the size of the user;

a connecting member (14) including an upper connecting member (24) and a lower connecting member (18 of 14) which form a pair fully capable of immobilizing a region from the ankle to the portion below the knee, depending on the size of the user;  
and

a knee fixing member (16) fully capable of immobilizing the region from a knee to the middle portion of a femur, depending on the size of the user,

wherein the foot fixing member, the connecting member and the knee fixing member can be used individually or cooperatively by being coupled to each other.

Graham does not specify that bolts couple the splint members to each other.

De George discloses a combined splint assembly for immobilizing an injured body part, wherein splint members are coupled to each other with bolts, to provide a secure connection.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the splint disclosed by Graham, wherein the splint members are coupled by bolts, as taught by De George, to provide a secure connection.

Regarding claim 2, Graham in view of De George disclose each and every structural element of the orthosis set forth in claim 2. Graham discloses a foot fixing member, a connecting member and a knee fixing member, but is silent as to the method of making these splint members. The claimed phrase "are injection molded" is being treated as a product by process limitation; that is, that the foot fixing member, connecting member and knee fixing members are made by injection molding.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Graham is silent as to the process used to make the splint members, it appears that the product in Graham would be the same or similar as that claimed; especially

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since both applicant's product and the prior art product are made of rigid materials intended to immobilize the limb.

In the alternative, it would have been obvious to one skilled in the art at the time the invention was made to have provided the splint disclosed by Graham in view of De George, wherein the splint members are formed by injection molding, as taught by U.S. Patent Number 3,955,565 to Johnson, to accurately custom form a splint to fit a desired body portion.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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